Bioethical Frontiers & Challenges in Tort & Criminal Law

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Our Anglo-American Legal Heritage protecting human life

Common Law, Homicide law, Quickening, Born Alive Rule (evidentiary)

How *Dobbs* Gave Us Back Our Legal & Cultural Heritage. 142 S.Ct. 2228 (2022)

Informed Consent

- Defined: Informed consent involves the legal duty that a doctor (technician, proprietor, distributor) owes to a patient/client to provide adequate information about the risks and benefits of procedures before launching the procedure. HOWEVER, *elective* procedures *should* require a higher standard of informed consent than *therapeutic* procedures, but the law is ambiguous and the issue is not settled. This has direct implications for abortion, "trans" surgeries, and new technologies that are designed to enhance or change bodily function. Some states have enacted special informed consent statutes for specific elective procedures, such as breast implants, vasectomies,
- When you decided to accept or reject a COVID-19 vaccine, did you feel that your decision was based on fully-informed consent?
- Possible Harms
    - Researchers and physicians are not required to disclose intangible hazards associated with investigatory study.
        - Emotional distress
        - Lost opportunity cost
        - Breaking of trust and confidence in research process
        - Clinical trial abandonment
        - Loss of meaningful choice about use of one's body as an experimental object
        - In the case of abortion, it is not necessary to disclose potential psychological effects of the procedure.
    - Incremental Risks
    - Information provided for consent is typically in a form that does not allow complete understanding for the average person to make a reasoned choice.
        - Communicating complex information
        - Lack of understanding of statistical terms that frame the scope of potential harm ("risks" or "probability")
        - Duty is met by sharing of information not actual understanding of patient

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- Does not require researcher to disclose economic interest in study
- Non-surgical procedures do not require informed consent in some states even though they may include touching capable of constituting battery.
- Genetic testing and the balancing of interests between the value of the collected information and privacy of the patient
    - National genetic databases
    - Insurance issues
- "Therapeutic privilege" – doctors need not look beyond the medical needs of their patients when providing information.
- Overtreatment leading to lost time and money
- One treatment is chosen without disclosing differences in pricing
- Autonomy overrules all other values rather than the broader ethical implications
- Informed consent gap as it pertains to racial, ethnic, and religious groups
    - Physicians may filter what information is shared
    - Standardization of informed consent requirements does not allow for context-specific ethical questions.
    - Assume all people need, want, should have autonomous control
- Transgender issues in children and risks of transitioning prior to natural puberty
    - Informed consent typically requires parental release, but exceptions are proposed for both abortion and transgender cases.

- Leading Cases
    - *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914) ("[e]very human being of adult years and sound mind has a right to determine what shall be done with his [or her] own body.").
    - *Natanson v. Kline*, 350 P.2d 1093 (Kan. 1960).
    - *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972) ("[a] risk is material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk in deciding whether or not to forego the proposed therapy.").
    - *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070-71 (S.D. Fla. 2003) (disclosing economic interest is not required in informed consent).
    - *Morgan v. MacPhail*, 704 A.2d 617 (Pa. 1997) (non-surgical procedures do not require informed consent).
    - Courts differ on whether informed consent requires disclosure of experience level of doctor (*Howard v. University of Medicine and Dentistry of New Jersey* as a opposed to *Whiteside v. Lukson*).

- Federal Legislation
    - 45 C.F.R. 46.116(b)(5); 21 C.F.R. 50.25(b)(5) – "Common Rule" regulation providing a catch-all requirement for renewed disclosures to already participating subjects by requiring that subjects be told about "significant new findings developed during the course of the research which may relate to the subject's willingness to continue…."
    - 16 CFR § 1028.116 - General requirements for informed consent.

- 38 CFR § 17.32 - Informed consent and advance directives.
- Cures Act

- State Legislation
  - Many states have a statute that defines the expectations of what informed consent requires based on a "reasonable person" standard.
  - Abortion and Informed Consent Statutes – "Women's Right to Know Laws" exist in over 30 states.
    - Wis. Stat. Ann. § 253.10 – what is required for informed consent specifically in the context of abortion.
    - Heartbeat Informed Consent Act (2012 OK. ALS 159, 2012 OK. Laws 159, 2012 OK. Ch. 159, 2011 OK. SB 1274) requiring certain providers to make the heartbeat of unborn child audible as a part of informed consent.
    - Missouri (§ 188.039 R.S.Mo.) requires a 72-hr waiting period as a part of informed consent when seeking an abortion.
    - At least ten states include gestational age at which the unborn baby is able to feel pain.
    - South Dakota requires standardized language for informed consent
  - Courts are divided on whether an embryo is a human being, and therefore, whether consent is relevant in the context of genetic engineering.

- Law Review Articles
  I. Douglas Andrew Grimm, Informed Consent for All! No Exceptions, 37 N.M.L. REV. 39 (2007)
  II. Sarah Polcz & Anna Lewis, CRISPR-CAS9 and the Non-Germline Non-Controversy, 3 J.L. & Biosciences 413, 413-14 (2016) – informed consent issues in genetic testing.
  III. Richard S. Saver, Medical Research and Intangible Harm, 74 U. CINN. L. REV. 941 (2006) – investigates harms that are not addressed in attaining informed consent.
  IV. Nadia N. Sawicki, Modernizing Informed Consent: Expanding the Boundaries of Materiality, 2016 U. ILL. L. REV. 821 (2016)

Assisted Reproduction

Description:

- gamete intrafallopian transfer (GIFT)
- zygote intrafallopian transfer (ZIFT)

Possible Harm:

Scientists in GB in May announced the birth of a child with three genetic parents.

In vitro fertilization (IVF) (1978)

Federal legislation: Fertility Clinic Success Rate & Certification Act (1992)

Embryos are treated as property by courts, governed by contract, absent statute.

- Unless state statute
- Embryo Adoption
- Embryo Custody

Prenatal diagnosis

Surrogacy

- Risks to women
- Intensive testing and fertility medications
- Medical complications of multiple pregnancy
- Risks to children
- Governed by contract and state law.

Leading Cases:

- In Re Baby M, 109 N.J. 396, 537 A.2d 1227 (1988)
- In re Marriage of Buzzanca, 61 Cal.App.4th 1410 (Cal. 1998)
- J.F. v. D.B., 879 N.E.2d 740 (Ohio 2007)
- RWS & BCF v. [surrogate] (Wis. SC 2010)

Federal legislation: very little.

State Regulations: diverse, but very little.

Leading cases

Skinner v. Oklahoma, 316 U.S. 535 (1942)

Federal Legislation

CLIA

Federal Prenatally and Postnatally Diagnosed Conditions Act, Pub. Law. 110-374

State Legislation:

- Limits on IVF, surrogacy

Genetic Modification (Engineering)

- Defined: Genetic modification involves the alteration of genetic material within an organism to alleviate a particular abnormality or to select for a particular trait. The issues pertaining to this development center primarily on the interests of the human embryo as well as the implicit risks associated with these procedures being relatively unknown.
- Possible Harm
  - Requires IVF procedure, and is therefore susceptible to the scope of harms that fall under IVF.
  - Unpredictability of modification

        - Off-target effects: occurs when a scientist, intending to edit one gene, inadvertently edits another gene instead or in addition to the target gene. (Includes mosaicism concerns)
        - Long-term medical effects that are not yet known
    - Currently offers very little added benefit to traditional treatment methods.
    - Eugenic Concerns: sex, race, and disability detection may influence whether a pregnancy is terminated. The question of what constitutes as a "disease" is also relevant.
    - Access-related concerns and heightened economic disparity.
    - Commodification of children.
    - Lacks consent of unborn subject.

- Leading Cases
    - Litigation has not arisen regarding FDA jurisdiction over genetic modification specifically; however, the courts have ruled in favor of the FDA's jurisdiction previously in stem cell research and regenerative medicine techniques indicating a federal interest.
        a. *United States v. Regenerative Scis.*, 741 F.3d 1314, 1317-21 (D.C. Cir. 2014)
        b. *United States v. US Stem Cell Clinic*, 403 F. Supp. 3d 1279, 1285-1301 (S.D. Fla. 2019)
    - *Skinner v. Oklahoma*, 316 U.S. 535 (1942).
    - *Wisconsin v. Yoder*, 406 U.S. 205, 233-34 (1972) (parental rights over children).
    - *Parham v. J.R.*, 442 U.S. 584, 603 (1979) (limitations on parental rights for scientific research on their children).

- Federal Legislation
    - Dickey-Wicker Amendment (1996): limits federal funding to controversial research such as the creation and destruction of embryos; prevents federal funding for creation of embryos or embryonic research; Balanced Budget Down Payment Act, P.L. No. 104-99, sec. 128, 110 Stat. 26, 34 (1996)
    - NIH's Recombinant DNA Advisory Committee refuses to "entertain proposals to modify the human germline." (published on official website)
    - Federal Food, Drug, and Cosmetic Act / Public Health Service Act (as applied to stem cell research)

- State Legislation
    - Ban on disability and sex-based abortions
        a. North Dakota was the first to introduce these types of bans (N.D. Cent. Code § 14-02.1-04.1 (2016)), followed by Indiana and Missouri.
        b. Ariz. Rev. Stat. § 13-3603.02 (2022): Class 6 felony for performing an abortion knowing the procedure is sought pursuant genetic selection based on sex, race, or genetic abnormality with the exception of a medical emergency.
        c. 11 states have enacted a ban on a sex-based abortions.

- Regulating medical procedures is typically in the purview of state power.

- Law Review Articles
  I. Myrisha S. Lewis, Is Germline Gene Editing Exceptional? 51 SETON HALL L. REV. 735 (20XX)
  II. Gary E. Marchant, Legal Risks and Liabilities of Human Gene Editing, 13 SCITECH LAW. 26, 27-29 (2016) (discussing the prospective causes of action available to those injured through germline gene editing research or clinical use).
  III. Myrisha S. Lewis, The American Democratic Deficit in Assisted Reproductive Technology Innovation, 45 AM. J.L. & MED. 130, 131-32, 149-55 (2019)
  IV. Andrea Boggio, Cesare P.R. Romano, & Jessica Almqvist, The Regulation of Human Germline Genome Modification (HGGM) at the National Level: A Call for Comprehensive Legal Reform, 43 LOY. L.A. INT'L & COMP. L. REV. 201 (20XX)

Neuroscience: Protecting the Mind

- Defined: The accessibility and capacity to influence the human mind through neurotechnology. Issues arising from this area of law relate primarily to privacy concerns.
- Possible Harm
  - Criminal Law: Attempts to explain away criminal liability (free will and the use of neurotechnology, agency issues)
    - Lacks perfect predictability and controllability
    - Lack of agency due to loss of personal identity
      a. Brain hacking through BCI-driven technology
      b. Foreseeability of outcomes inherent in these devices; unanticipated subconscious thought
    - Use as evidence: "Varying scientific certainty standards, the use of jargon, problems in the translation of neuroscientific evidence, and the use of group averaged data applied to an individual." (Nadine article) and *mens rea*
  - Biological linkage between criminal behavior and genetics are weak
  - Discriminatory implications on insurance coverage
  - Mental privacy concerns
    - Neural data / Mental data (ex: monetary exploitation through info collected on social media, brain mapping)
    - Consciousness, personal autonomy, and cognitive liberty
  - Neurotechnology as an extension of product liability (some cross-over with AI concerns)

- Leading Cases (federal and state)
  - *United States v. Semrau*, 693 F.3d 510, 523-24 (6th Cir. 2012).
  - *People v. Weinstein*, 591 N.Y.S.2d 715, 718 (App. Div. 1992).
  - *Katz v. United States*, 389 U.S. 47 (1967).
    - Expectation of privacy of one's mind may be similar to property.

- *Sexton v. State*, 997 So. 2d 1073, 1082-85 (Fla. 2008) (brain imaging introduced when defending severe crimes).
- *Schmerber v. California* 384 U.S. 757, 764 (1966)
    - Brain data as testimonial rather than a physical entity may allow for protection
- *Pennsylvania v. Muniz* 384 U.S. 757, 764 (1966).
    - Defendant was not required to share "thoughts and feelings" with the gov.

- Federal Legislation: neurotechnology is not explicitly mentioned, but human rights legislation pertaining to privacy and personal autonomy may be relevant.
    - Human rights legislation regarding genome and genetic data such as Universal Declaration on the Human Genome and Human Rights and International Declaration on Human Genetic Data may indicate the direction of neurolaw
    - Fourth Amendment concerns and right to privacy
    - Fifth Amendment concerns
    - Copyright laws and neuro data in tangible forms
    - Privilege of requiring examination could be extended to neuro testing 18 U.S.C. § 4241(a) (2006).

- State Legislation
    - Minnesota: 2021 House Bill regarding neuro-data rights and civil / criminal remedies for breach was introduced, but failed

- Law Review Articles
    I. Timo Istace, LL.M., Neurorights: The Debate About New Legal Safeguards to Protect the Mind, 37 ISSUES L. & MED. 95 (2022) (comprehensive overview)
    II. Francis X. Shen, Privacy, Security, and Human Dignity in the Digital Age: Neuroscience, Mental Privacy, and the Law 36 HARV. J.L. & PUB. POL'Y 653 (20XX)
    III. Nadine Liv, Neurolaw: Brain-computer interfaces, 15 U. ST. THOMAS J.L. & PUB. POL'Y 328 (2021)
    IV. Laura Cabrero & Jennifer Carter-Johnson, Emergent Neurotechnologies and Challenges to Responsibility Frameworks, 54 AKRON L. REV. 1 (2020)

Changing Personal Identity

- Defined: Americans are regularly concerned about "identity theft." A question of whether certain changes result in a difference in culpability over time. If personal identity changes over time, then aspects of the criminal law may need to be more malleable to maintain a just system.
- Possible Harm
    - Criminal law punishes equally both current and future 'self'
        - Overcriminalization
        - Overincarceration
        - Personal identity does not stabilize until after juvenile sentencing has expired

        - Developed disorders that taint memory of committing crime causing punishment to lose deterrent or rehabilitative capacity.
    - Punishment is immoral if there is a lack of responsibility for a crime; this responsibility may be present for an identity at the time the crime is committed and yet dissipate as identity evolves.
        - Criminal law uses synchronic identity (single moment), while mankind may more accurately have a diachronic identity (over time)
        - Psychological connectedness changes by degrees v. bodily continuity
        - Punishment may hold despite a lapse in memory which may warrant conversations of whether this is cruel and unusual

- Leading Cases (federal and state)
    - *Madison v. Alabama* (*Madison I*), 139 S. Ct. 718 (2019) (No. 17-7505), 2018 WL 3655848.
    - *Madison v. Comm'r, Ala. Dep't of Corr.* (*Madison II*), 851 F.3d 1173, 1179 (11th Cir. 2017).
    - *Parker v. State*, 597 S.W.2d 586, 587, 589 (Ark. 1980) (multiple personalities at a single instance of time cannot exonerate criminal identity); *see also Lamar, Archer & Cofrin, LLP v. Appling*, 138 S. Ct. 1752, 1758 (2018) (bankruptcy sufficiently breaks necessity to repay while affirming other legal identities as culpable).
    - *Graham v. Florida*, 560 U.S. 48, 74 (2010) (finding life without parole for juvenile cruel and unusual).

- State legislation: very little.
- Law Review: Mihailis E. I Diamantis, Limiting Identity in Criminal Law, 60 B.C. L. REV. (2011)

Artificial Intelligence (AI)

- Defined: 2023 has been the year of AI. Encapsulates a class of technology mimicking the processes occurring within the human mind which has implications primarily for who holds responsibility for a harm directly or indirectly caused by AI as well as the implications of how these algorithms operate.
- Artificial General Intelligence (AGI)
- "Narrow AI" = designed to do one thing, such as drive a car (e.g., Deep Blue chess)
- "Machine learning" depends on algorithms ("a precisely defined set of mathematical or logical operations for the performance of a particular task" (OED))
- "Deep learning": run multi-layer neural networks
- Use of robots
- We have all benefitted from the use AI. Most "smart" technologies use AI.
    - Amazon uses algorithms to trace the products you buy.
    - Algorithms sort through job applications.
    - Database of x-rays of lungs that compares yours and make diagnosis based on visual patterns.
    - facial recognition

- How might AI threaten ethical limits?
    - Some affirm that we are "nowhere near….approaching the level of human intelligence" (Emeritus Professor Danny **Crookes,** Queen's University Belfast)
    - Crookes: "Even if we knew the rules of human reasoning, how do we abstract from a physical situation to a more abstract formulation so that we can apply the general rules of reasoning?"
    - Crookes: "How can a computer build up and hold an internal mental model of the real world?"
    - Crookes: "Humans have a general-purpose ability to visualize things and to reason about scenarios of objects and processes…it is a key requirement for real intelligence, but it is fundamentally lacking in AI systems."
- Possible Harms
    - AI and product liability in tort cases – could result in a lack of liability if device is deemed necessary but harm was unintended.
        - Ex: automatized driving, delivery drones, stock investments, medical history analysis
        - Manufacturer or operator as agent
        - Negligence, strict liability, or personhood liability of the AI (as a superseding cause)
        - Difficulty in assessing foreseeability in manufacturer liability
    - Loss of jobs through replacement of human tasks with machines
    - Filter bubbles
        - Affects where and what you buy
        - Disinformation
    - Mass surveillance and storing of information as machine learns
    - Potential error in identification (fake videos, or misidentification in criminal investigation)
    - Pre-coded or determined moral choice
        - Loss of autonomous agency through algorithmic biases
        - Machine-learning and pre-coded algorithm may conflict

- Leading Cases (federal and state)
    - *Riegel v. Medtronic*, 552 U.S. 312 (2008).
    - *Hendricks v. United States*, 140 Fed. Cl. 496, 499 (Fed. Cl., 2018) (dismissing complaint that alleged an artificial intelligence computer system "stole [her] thoughts")

- Federal Legislation – no comprehensive legislation exists
    - President Trump issued Executive Order 13859, *Maintaining American Leadership in Artificial Intelligence*
    - FAST Act
    - National AI Initiative Act of 2020
    - Section 5 of the FTC Act may be used for biased algorithms

- State Legislation
    - Task forces created by state legislation in Vermont, New York, Alabama, and Washington DC
    - California Consumer Privacy Act – requires transparency in how data collected by AI is used
    - Artificial Intelligence Video Interview Act, HB 2557, 820 Ill. Comp. Stat. Ann. 42 (2019) – regulates AI as used in employment interviews
    - 45 States have legislation regarding automated vehicles
    - Colorado (CO S.B. 169) prohibits insurers from using AI algorithms that unfairly discriminate

- Law Review Article: Scott J. Shackelford & Rachel Dockery, Governing AI, 30 CORNELL J. L. & PUB. POL'Y 279 (2020).

Conclusions:

We have an Anglo-American heritage protecting human life from its earliest development.

Understanding the nature and scope of technology—its power and limits—is essential.

Federalism can help preserve freedom and human dignity.

It's important to put ethical limits on technology before interest groups render it limitless.

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